

REMARKS

Claims 1-21 are active. Claim 12 is rejected under 35 USC 102 as being anticipated by Diamantopoulos. Claims 1-3 and 9-10 are rejected under 35 USC 102 as being anticipated by Kenney. Applicant notes with appreciation that claims 4-8, 11, and 13 -21 are deemed to contain allowable subject matter. The drawings are objected to on the form sheet PTOL 326, but no substantiating reasons are given for the objection.

Enclosed is a letter to the Official Draftsperson enclosing 7 sheets of formal drawing to be substituted for the drawing now in the case. Applicant believes that these formal drawings will correct any deficiencies in the prior drawings that may have been intended by the Office Action.

Enclosed is a form PTO 1440 filed in the parent application serial no. 09/716567 and a Notice of References Cited form PTO 892 also taken from the parent application noted. The Examiner is respectfully requested to acknowledge he has reviewed the cited references and forward a copy of these forms with his acknowledgement as required by the rules. No copies of the references need be provided according to the rules, MPEP 609I.A.2. These forms are filed herewith so that the references will be printed in the patent document.

Applicant traverses the rejection of claim 12 over Diamantopoulos ('504). Claim 12 is directed to a method of correcting a bunion condition in a foot.

Claim 12 calls for:

A method of correcting a bunion condition in a foot comprising the step of applying an electrical signal to the abductor digiti minimi brevis muscle to strengthen the abductor digiti minimi brevis muscle and counter balance the strength of the flexor digitorum muscle to correct for an imbalance between

the two muscles. (underlining added)

The Office Action states that '504 applies an electrical signal to the abductor digiti minimi brevis muscle to strengthen the abductor digiti minimi brevis muscle and counter balance the strength of the flexor digitorum muscle to correct for an imbalance between the two muscles. The Action also refers to Fig. 9, the abstract and column 10, lines 24-28.

Applicant has carefully reviewed this reference and the referred to locations thereof. Applicant fails to find either anticipation of claim 12 or any suggestion of this claimed method in this reference and especially at the designated locations.

The reference does not apply an electrical signal. Col. 10, lines 24-28 do not disclose much less suggest what is claimed. This portion of the disclosure of '504 does not disclose applying an electrical signal as claimed. This reference discloses at the referenced location:

A patient had . . . extreme pain in the right big toe . . . [and] was found to have a congenital Hallux Valgus or chronic "bunion". The sore toe was treated with a multi-diode biostimulation device . . . (660nm, 820nm, 880 nm, 950nm). The patient experienced immediate relief of all pain . . .

As stated in the Abstract, the biostimulation device comprises an array of substantially monochromatic radiation sources of a plurality of wavelengths, and preferably at least three different wavelengths. All the above excerpt discloses is that some portion of the "sore" big toe was exposed to electromagnetic radiation and pain was relieved. It is believed that the pain was relieved by heat therapy and not by muscle stimulation with an electrical signal.

The reference does not state that the abductor digiti minimi brevis muscle received such radiation and if it did, it is believed the radiation would generate heat and would not result in stimulation of the muscle as claimed. Radiation induced heat is not the same as an applied electric current signal. The conclusion of the Action is proscribed as it is only arrived at in view of applicant's disclosure. Further, this excerpt only states that pain was relieved, typical of heat therapy, not that the bunion condition was corrected which would not occur from heat therapy. There is no basis in this reference that the muscles were acted on as claimed. This is an assumption not based on the reference disclosure.

Exposing a sore toe to electromagnetic radiation to relieve pain via induced heat from IR radiation does not mean or imply that the bunion condition in fact was corrected. The reference does not state the condition was corrected. Many sources of pain can be relieved, especially by radiation induced heat, but the condition causing the pain can remain. Relief of pain is not the same as correcting the condition causing the pain. The reference does not go so far and does not support this conclusion.

The cause of the pain is not explained in '504 and the application of a pain relieving radiation, which may include application of heat or the equivalent of heat, notoriously used to relieve painful muscles, does not infer that the bunion muscle condition causing the pain was corrected.

Visible (light) or non-visible electromagnetic radiation is not an electrical signal in the context of claim 12. An electrical signal is one in which a current flows in the form of flowing electrons in a conductor. Electromagnetic radiation is not an electrical signal in the context of such a current. No current flows in such radiation. The term "electrical"

means "related to or associated to with electricity." McGraw Hill *Dictionary of Scientific and Technical Terms*, 1974. An electric circuit is a "path or group of interconnected paths capable of carrying electric currents." Same dictionary. Radiation on the other hand is defined as "The emission and propagation of waves transmitting energy through space or through some medium." Same dictionary. Applicant's disclosure applies the current signal with electrodes. Radiation is not applied with electrodes.

Claims are construed according to the plain meaning of terms is used. See MPEP 2111.01. Plain meaning is the meaning applied by one of ordinary skill in the art unless the applicant has given the terms a different meaning. The specification is consistent with this plain meaning of the term electrical signal. Applicant's disclosed device employs electrical currents with contact pads. These signals stimulate muscles with electrically conductive currents. Radiation of the reference is believed to be in the infrared portion of the light spectrum and is believed to provide heat therapy, not muscle stimulation.

To give the term "electrical signal" a different meaning so as to include radiation is contrary to the Fed. Cir. decisions on claim interpretation. See the MPEP. Should the Examiner be of the opinion that the claimed electrical signal includes radiation, then the patent specification makes clear that radiation is not included in such a definition and should be so deemed by the Examiner, MPEP 2111.01. For example, fiber optics conduct electromagnetic waves in the form of visible light. One of ordinary skill would not consider such light signals as electrical signals. Electrical signals connote electrical conductors for the flow of electrons not propagating waves, e.g., wires, not radiation.

Radiation is not coupled by electrical conductors, but by light transmitting space. These are not the same. For the reasons given claim 12 is believed allowable.

Claim 1 is rejected as anticipated by Kenney. Applicant traverses this rejection in that this reference does not suggest much less anticipate claim 1. Kenney is cited as anticipating claim 1. This is not true. Kenney does not disclose what is claimed. Anticipation requires the claim to be expressly disclosed in a single reference. At most Kenney is an invitation to experiment, hardly an anticipation.

Kenney is cited as disclosing a device Fig. 20 for applying an electrical signal to the abductor digiti minimi brevis muscle in the foot for strengthening the abductor digiti minimi brevis muscle to counter balance the strength of the foot flexor digitorum muscle to correct a bunion in the small toe. Applicant disagrees that Kenney discloses such a device. The Office Action refers to Fig. 20 of the reference. There are no electrodes shown in Fig. 20 for applying such a signal as claimed. Fig. 20 is described at col. 10, lines 47-54 and at col. 21, lines 34-66. This device is a mechanical arrangement not an electrical device for applying electrical signals as claimed. The figure 20 device 506 is for treating contracture of a foot at the ankle relative to the leg. Contracture is shortening of a muscle or scar tissue producing distortion, a deformity or abnormal limitation of movement of a joint. This figure is foreign to treating a bunion condition and the only nexus of this figure to applicant's claim 1 is that it involves the foot.

However, the Office Action refers to column 4, lines 30-31 which merely refers to the use of strategically placed electrodes. This portion does not identify what such strategic places are. The Office Action refers to Fig. 27. But this figure relates to the arm

not to the claimed muscles. This appears to be a suggestion to do what is claimed as asserted by the Action, but a suggestion is not anticipation. This rejection based on section 102 clearly is misplaced. There is no nexus between Fig. 27 and Fig. 20 except that provided by applicant. Using applicant's disclosure as a guide is proscribed. There is no anticipation by this reference.

The Action also refers to col. 7, lines 45-52. However, this section merely reiterates that the electrotherapy is applied to strategic places and does not identify such places at this point in the specification. This section merely states that electrotherapy is beneficial without identifying the particular muscles as claimed. This is a proscribed invitation to experiment.

A reference that only invites experimentation is not a valid reference. MPEP 2144.05. This references do not suggest a result effective variable to correct a bunion condition since there is no teaching therein of such a condition and whether or not such a condition is so correctable generally with electrical stimulation. With no such suggestion, this reference is a mere invitation to experiment, which is not a test of obviousness. *In re Antonie*. MPEP 2144.05. There are countless muscles in the body and, in the Fig. 20 device, there is no suggestion of the particular claimed muscles associated with therewith. There must be a suggestion to modify the reference, MPEP 2143. This is not provided by the reference and thus is plainly not an anticipation.

The Action also refers to Fig. 27 which is the arm and not the foot much less the claimed muscles. Then the Action refers to Fig. 20 which is not relevant to the Fig. 27 embodiment except as provided by applicant. The reference per se does not suggest

much less anticipate what is claimed absent applicant's disclosure. No motivation is provided. The Office Action repeatedly refers to the claimed muscles in referring to this reference but nowhere in this reference are these muscles identified. Applying electrical signals to desired body parts does not identify the condition which causes the bunion. Neither reference identifies the condition which causes the bunion, and therefore do not provide the claimed solution.

More importantly, the fallacy of the position of the Office Action is that it was not known in the medical field to one of ordinary skill in the art of podiatry that muscle unbalance is the cause of the bunion condition, and more further removed, which muscles. This recognition of the cause of the problem is the basis that the claimed subject matter is patentable.

It is the recognition of the CAUSE OF A PROBLEM that gives rise to patentable subject matter. See MPEP 2141.02 stating "the claimed invention as a whole must be considered" and that "discovering the source/cause of a problem is part of the 'as a whole' inquiry." "[A] patentable invention may lie in the discovery of the source of the problem even though the remedy may be obvious once the source of the problem is identified. This is part of the subject matter as a whole which should always be considered in determining obviousness of the invention under 35 U.S.C. §103." (Citing case) The Office Action does not cite a single reference that discloses that the source of the bunion condition is due to muscle unbalance and if such unbalance does exist, which muscles are involved. The references do not go so far. Thus the conclusion of the Office Action does not follow the precedent mandated by the MPEP.

Exhibit A is a copy of a text entitled "Family Health and Medical Encyclopedia, Reader's Digest," prepared in association with Dr. Benjamin F. Miller, associate professor, University of Pennsylvania, School of Medicine, copyright 1970. At pages 541- 542, this text states that a bunion is the painful deformity of the big toe caused by shoes that bend this toe inward toward the smaller toes, putting pressure upon the joint connecting the big toe with the foot. An illustration shows that the condition is corrected by surgery requiring a bone to be removed. This teaches away from what is claimed, the antithesis of obviousness.

Thus it was not recognized by the prestigious University of Pennsylvania medical staff that the bunion condition is a result of or could be the result of muscle unbalance as taught by the present inventor. This belies any conclusion that it would be obvious to one of ordinary skill to do what is claimed, since one of ordinary skill would not use electrical stimulation, but surgery to correct the bunion condition. The level of skill of a person of ordinary skill in the art is also presumed to be one who thinks along the line of conventional wisdom and is not one who undertakes to innovate, whether by patient, systematic research or extraordinary insights, it makes no difference which. Phillips Petroleum v. U.S. Steel, 6 USPQ 2d 1065 (D. Ct. Del. 1987). (Citing cases). The present claimed invention thus goes against the conventional wisdom of others of ordinary skill in the podiatry art and thus is not obvious to such persons.

Exh. B is a letter dated November 19, 2003 from Howard J. Hillstrom, Phd., associate professor and Director of the Gait Study Center at Temple University School of Podiatric Medicine stating that he met with the present inventor regarding the subject

claimed invention. Dr. Hillstrom states that FES (functional electrical stimulation) has been used for a wide variety of applications including treating paralyzed individuals, for pain management, for delivering pharmaceutical agents transdermally and so on. He further states that he has never seen any article or abstract that has applied electrical stimulation techniques for non-invasive treatment of hallux abductovalgus (HAV) or the bunion deformity. He expresses the opinion that the claimed treatment is novel.

Attached as Exh. C is the CV of Dr. Hillstrom. As a result of his work and experience as shown in Exh. C, he is very familiar with the pathological condition referred to as the bunion condition of the foot. In view of the above, the references do not teach or suggest what is claimed.

The claim is not applying signals to the foot, which has numerous muscles, but to specific muscles. No reason is given as to why it is obvious to apply the signals as claimed to specific muscles. The Office Action is silent to this. This is not a proper basis for the rejection.

Neither reference points one of ordinary skill as to the cause of a bunion condition in the foot or how to correct such a condition.

A bunion condition as disclosed by applicant is caused by one muscle being stronger than another muscle in the foot causing the condition.

There is no discussion in the references as to the cause of a bunion condition nor is there any discussion relating to how to correct for a bunion condition. The disclosed apparatuses are not directed to correcting such a condition. There is no relevant teaching to one of ordinary skill of either the cause of a bunion condition, and, even if such cause

were known, there is no teaching or disclosure of the concept of correcting such a condition. The references do not disclose that such a condition is correctable, and even more remote, plainly the disclosed electrical stimulation apparatus will not correct such a condition, since it is not capable of applying signals to the claimed muscle much less signals of the correct value. In other words, simply because it is known to stimulate muscles can not be extrapolated to manifest that the claimed muscle will be sufficiently strengthened by this process to over come and correct the bunion condition. The references do not go so far and is at best an invitation to try, which is proscribed.

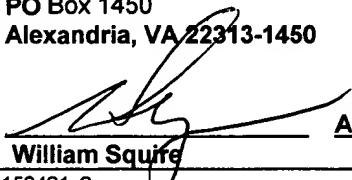
Discovering the source of the problem is part of the invention of a whole that needs to be considered. The problem is bunions. Neither cited reference is concerned with this problem. MPEP 2141.02, page 2100-120, 121. The source of the problem is the recognition that the abductor hallucis muscle is weaker than the adductor hallucis muscle and is the cause of the condition and that by strengthening the abductor hallucis muscle would alleviate the problem. The knowledge that generally electrical signals can alleviate certain muscle problems, the abdominal, leg and arm muscles, is of no help in this context. The references do not teach or suggest what is claimed.

The prior art must be considered in its entirety including that which teaches away. MPEP 2143.03 page 2100-122. To establish *Prima facie* obviousness, there must be some suggestion or motivation in the prior art to do what is claimed. MPEP 2143. See *In re Fine* cited by the MPEP. The fact that the references disclose different elements of the claimed combination is insufficient if there is no motivation to combine them. The suggestion to combine must come from the references. Claim 1 is believed allowable.

Claims 2-11 depend from claim 1 and are believed allowable for at least the same reasons in addition to the fact that claims 4-8, and 11 are deemed to contain allowable subject matter.

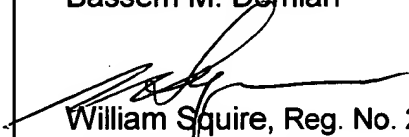
Enclosed is a request for a one month extension of time to respond to the Office Action and a check in the amount of \$55.

If any additional fee is due for this paper, the Commissioner is authorized to charge deposit account 03-0678 with respect to any underpayments or to credit that deposit account for any overpayments.

<u>FIRST CLASS CERTIFICATE</u>	
I hereby certify that this correspondence is being deposited today with the U.S. Postal Service as First Class Mail in an envelope addressed to:	
Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450	
 William Squire	April 7, 2004 Date

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Respectfully submitted,
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